

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

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COMMENTS:

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Via Certified Mail



March 9, 2012

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
Attn: Section 8(e)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: TSCA Section 8(e) Notification of Substantial Risk: Triethoxy(3-thiocyanatopropyl)silane (CAS No. 34708-08-2)

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances and Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, the Silicones Environmental, Health and Safety Council (SEHSC)¹ submits, on behalf of its member companies, information concerning two studies with Triethoxy(3-thiocyanatopropyl)silane (CAS No. 34708-08-2). Neither SEHSC, nor any member company, has made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings

Chemical Substance

Triethoxy(3-thiocyanatopropyl)silane (CAS No. 34708-08-2)

Study Titles

1. Final report: *In Vitro* Mammalian Gene Cell Mutation Assay Thymidine Kinase Locus (TK +/-) in Mouse Lymphoma L5178Y cells with Triethoxy(3-thiocyanatopropyl)silane
2. Draft report: *In Vitro* Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with Triethoxy(3-thiocyanatopropyl)silane

¹ SEHSC is a not-for-profit trade association whose mission is to promote the safe use of silicones through product stewardship and environmental, health, and safety research. The Council is comprised of North American silicone chemical producers and importers.

CONTAINS NO CB

Summary

Results from an in vitro mammalian gene cell mutation assay conducted with Triethoxy(3-thiocyanatopropyl)silane (CAS No. 34708-08-2; the test substance) indicate the test substance is mutagenic, but not clastogenic. Results from an in vitro mammalian chromosome aberration test in Chinese Hamster V79 Cells indicate the test substance induced structural chromosomal aberrations and is considered to be clastogenic.

Details

Study Design

1. *In Vitro* Mammalian Gene Cell Mutation Assay Thymidine Kinase Locus (TK +/-) in Mouse Lymphoma L5178Y cells with Triethoxy(3-thiocyanatopropyl)silane.

In an OECD test guideline 476 study, the test substance was investigated at the following concentrations: with metabolic activation: 0.05, 0.1, 0.2, 0.5, 0.7, 0.9, 1.1, and 1.3 mM and without metabolic activation: 0.005, 0.01, 0.02, 0.1, 0.2, 0.05, 0.5, and 1 mM. The experiment was performed as a 4- hour short term assay.

2. *In Vitro* Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with Triethoxy(3-thiocyanatopropyl)silane.

In an OECD test guideline 473 study, the test substance was investigated at the following concentrations for the microscopic analysis of chromosomal aberrations: without metabolic activation: 0.40, 0.60, and 0.80 mM; with metabolic activation: 0.15, 0.30 and 0.50 mM. The chromosomes were prepared 20 hours after treatment. Precipitation was noted at 0.80 mM in the absence of metabolic activation. Toxicity was noted in the absence of metabolic activation at concentrations ≥ 0.6 mM.

Results

1. *In Vitro* Mammalian Gene Cell Mutation Assay Thymidine Kinase Locus (TK +/-) in Mouse Lymphoma L5178Y cells with Triethoxy(3-thiocyanatopropyl)silane.

Precipitation was noted in the pre-experiment at a concentration of 2.5 mM. Growth inhibition was observed in the main experiment with and without metabolic activation. Positive control substances provided positive responses as expected, indicating the test was valid and sensitive. A biologically relevant increase of mutants was found after treatment with the test substance only in the presence of metabolic activation. The Global Evaluation factor (GEF; defined as the mean of the negative/vehicle mutation frequency plus one standard deviation) was exceeded by the induced mutant frequency at a concentration ≥ 1.1 mM in the main experiment with metabolic activation. A dose-response relationship was observed. Colony sizing showed no clastogenic effects of the test substance.

2. *In Vitro* Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with Triethoxy(3-thiocyanatopropyl)silane.

TSCA Section 8(e) Coordinator
US Environmental Protection Agency
March 9, 2012
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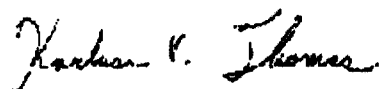
Precipitation was noted at 0.80 mM in the absence of metabolic activation. Toxicity was noted in the absence of metabolic activation at concentrations ≥ 0.6 mM. Positive control substances provided positive responses as expected, indicating the test was valid and sensitive. A clear increase of aberrant cells was found in the main experiment with and without metabolic activation at all concentrations evaluated. A dose-response relationship was observed. In the main experiment with or without metabolic activation, no biologically relevant increase in the frequencies of polyploid cells was observed after treatment with the test substance as compared to controls.

Action

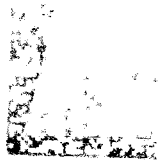
A copy of the final report "*In Vitro* Mammalian Gene Cell Mutation Assay Thymidine Kinase Locus (TK +/-) in Mouse Lymphoma Y5178Y cells with Triethoxy(3-thiocyanatopropyl)silane" is attached. A copy of the final report "*In Vitro* Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with Triethoxy(3-thiocyanatopropyl)silane" will be provided when it is available.

If you have any questions concerning this submission, please contact me at (703) 788-6570, kthomas@sehsc.com, or at the address provided herein.

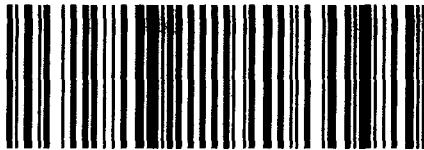
Sincerely,

A handwritten signature in cursive script, appearing to read "Karluss Thomas".

Karluss Thomas
Executive Director



CERTIFIED MAIL



7001 0360 0002 3429 7259



Silicones Environmental, Health and Safety Council
of North America

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